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10/551,070	09/27/2005	Richard D. A. Heal	05-783	6312
20/306 7590 03/29/2010 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606				
EXAMINER SIMS, JASON M				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/551,070

Applicant(s)

HEAL ET AL.

Examiner

JASON M. SIMS

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,10,11,16,17 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9,14,15 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election of the species of claims 15 and 18 in the reply filed on 1/7/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 16-17 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/7/2010.

Applicant's arguments, filed 8/26/2009, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 8/26/2009, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 1-2 and 10-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/5/2009.

Claims 3-9, 14-15, and 18 are the current claims hereby under examination.

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The following rejection is being newly applied which has been necessitated by amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 and all claims dependent therefrom comprise the limitation reciting "wherein said analyzer is adapted to select a set of channels, and perform feature extraction on each of said selected channels to form a feature set." Support for said analyzer being adapted to select a set of channels has not been found in the instant specification. Thus said newly added claim is being considered as new matter.

Claim Rejections - 35 USC § 103-modified

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-9, 14-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkolder (US P/N 6,377,057).

The claims are directed to a compound analysis system, the system comprising a micro-electrode array provided by a bio-compatible substrate having a plurality of electrodes situated thereon, said electrodes having an arrangement on said substrate corresponding substantially to that of an electrically active cellular network disposable in use thereon, a multi-channel amplifier coupled to said electrodes and an analyzer operatively connected to said amplifier to determine for each active channel a vector quantity having a number of dimensions equal to a number of features derived from the electrical output of said electrically active cellular network with each component of said vector being representative of a change in said feature, an apparatus, and a sensor.

Borkholder at Figs. 1-6 teach a compound analysis system, apparatus, sensor, and micro-electrode array as in claims 3-9. Borkholder at col. 1, lines 13-

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15 teach that using a cellular network cultured on electrode arrays is a well known technique in the arts. Borkholder at col. 2, lines 20-68 teaches studying different compounds and classifying the compounds and extracting features for classification of compounds using whole cell based biosensors. Borkholder at col. 3, teaches an apparatus having a processor being operable in response to signals derived from a micro-electrode array, a storage device and a sensor for compound detection.

Borkholder suggests, but does not explicitly teach for each active channel a vector quantity having a number of dimensions equal to a number of features derived from the electrical output of said electrically active cellular network with each component of said vector being representative of a change in a said feature.

Borkholder suggests this because Borkholder teaches at col. 3, lines 1-14, that the changes in electrical potential or ionic current are recorded and the data used to determine the spectral changes are generated, which are then used for later classification and the pattern responses are stored. Borkholder at Fig. 2 and col. 3, lines 33-37 teaches using a multi-channel amplifier, i.e. an 18 channel amplifier, which measure action potentials. In addition, Borkholder at col. 6, lines 25-36 teaches that the complete range of frequencies for the action potential is divided into bins for the purpose of calculating the power spectral density, which further suggests a multi-dimensional vector quantity for each active channel. Borkholder at col. 15, lines 5-7 further teaches that the system may perform spectral analysis of the resulting signals in order to monitor changes in various

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characteristics in real time, which further suggests multi-feature extraction.

Furthermore, Borkholder at col. 4, lines 6-20 teaches detection of a pattern of spectral changes, wherein the changes correlate with the effect on the channels of the responding cells. Therefore it is implied that the response pattern, i.e. vector quantity dimensions, correlates with the number of features derived.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to have stored a vector quantity of dimensions equal to the number of features derived from the electrical output for use in the analysis system as taught by Borkholder. This is because Borkholder teaches a system that stores the features derived from the electrical output, wherein each feature derived would have the designated storage space for being recorded as it is part of the routine programming and usage of a computer system to store the data being generated. Therefore, the differences between the claimed invention and the prior art were encompassed in known variations or in a principal known in the prior art.

Borkholder does not explicitly teach wherein said analyzer is adapted to select a set of channels, and perform feature extraction on each of said selected channels to form a feature set as in claim 14.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used an analyzer that was adapted to select a set of channels for use in the multichannel analyzer of the biosensor invention taught by Burkholder. This is because Burkholder teaches using an analyzer with a multichannel amplifier. Burkholder further teaches wherein signal monitoring

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may be configured to enable monitoring of an individual cell and the monitoring will vary according to the specific application. Burkholder at col. 14, lines 58-67 and col. 15 further teaches wherein the computer system will perform spectral analysis on the resulting signals in order to monitor changes in various characteristics. Therefore, one of ordinary skill in the art would immediately envisage selecting particular channels, i.e. those channels which produce a signal that is to be monitored, for signal processing. Therefore, having an analyzer adapted to being able to select a set of channels is an implied part of the process of signal processing. Furthermore, having an analyzer adapted to being able to select a set of channels is the product not of innovation, but of ordinary skill and common sense.

Borkholder does not explicitly teach wherein channels with the most frequently occurring non-zero number of spikes are selected.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have selected channels with the most frequently occurring non-zero number of spikes in the method of using biosensors to identify compounds as taught by Burkholder. This is because Burkholder at col. 14, lines 58-67 and col. 15 further teaches wherein the computer system will perform spectral analysis on the resulting signals in order to monitor changes in various characteristics. Channels with resulting signals that are to be monitored will inherently have the most frequently occurring non-zero number of spikes. Therefore, one of ordinary skill in the art would immediately envisage selecting particular channels, i.e. those channels with the most occurring non-zero number

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of spikes, to monitor and this success is not the product of innovation, but of ordinary skill and common sense.

Borkholder at col. 6 lines 1-8 teaches at analyzing peaks and frequencies of the output signal which reads on components representative of both local and global features across channels in claim 18, as defined by applicant at paragraph [0032] of their published application.

Response to Arguments

Applicant's arguments filed 8/26/2009 have been fully considered but they are not persuasive.

Applicant argues that Borkholder does not teach determining values for each channel, nor a multi-dimensional vector quantity for each channel.

Applicant's argument is not found persuasive because, as in the instantly claimed invention, Borkholder at Fig. 2 and col. 3, lines 33-37 teaches using a multi-channel amplifier, i.e. an 18 channel amplifier, which measures action potentials. In addition, Borkholder at col. 6, lines 25-36 teaches that the complete range of frequencies for the action potential is divided into bins for the purpose of calculating the power spectral density, which further suggests a multi-dimensional vector quantity for each active channel. Borkholder at col. 15, lines 5-7 further teaches that the system may perform spectral analysis of the resulting signals in order to monitor changes in various characteristics in real time, which further suggests multi-feature extraction. Thus as stated in the Office Action, although Borkholder does not explicitly teach for each active channel a vector

quantity having a number of dimensions equal to a number of features derived, it is suggested.

Applicant further argues that the total amount of data is greater in the present invention than that of the scale envisaged by Borkholder.

Applicant's arguments are not found persuasive because they are not commensurate in scope with the claimed invention. The instantly claimed invention does not recite generating greater amounts of data. Additionally, the recited limitation of a vector quantity having a number of dimensions equal to a number of features derived from the electrical output does not necessitate that more than one feature is derived. Therefore, it does not necessitate that the total amount of data being generated is considerably greater.

Again applicant further argues that Borkholder is not an obvious variation because the skilled person would not consider such an increment in terms of the quantity of information derived.

Applicant's arguments are not found persuasive because the instantly claimed invention does not recite generating greater amounts of data. Additionally, the recited limitation of a vector quantity having a number of dimensions equal to a number of features derived from the electrical output does not necessitate that more than one feature is derived. Therefore, it does not necessitate that the total amount of data being generated is considerably greater.

Applicant further argues that it would not have been apparent to one skilled in the art at the time of the invention as to how to modify the output format of Borkholder to incorporate the significant increase in data provided by the

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present invention or even whether such modification is possible. Applicant further argues that further inventive thought is required before attempting the multi-variable, multi-channel approach is taken.

Applicant's arguments are not found persuasive as Borkholder at Fig. 2 and col. 3, lines 33-37 already teaches using a multi-channel amplifier, i.e. an 18 channel amplifier, which measure action potentials and reads on a multi-channel approach. Furthermore, Borkholder at col. 6, lines 25-36 teaches that the complete range of frequencies for the action potential is divided into bins for the purpose of calculating the power spectral density, which further suggests a multi-dimensional vector quantity for each active channel. Moreover, the instantly claimed invention does not recite generating greater amounts of data. Additionally, the recited limitation of a vector quantity having a number of dimensions equal to a number of features derived from the electrical output does not necessitate that more than one feature is derived. Therefore, it does not necessitate that the total amount of data being generated is considerably greater.

Applicant argues that claim 9 is non-obvious because it is drawn to an electrode "array" associated with a "biocompatible substrate." Applicant specifically argues that Borkholder discloses in passing "electrically active living cells cultured on extracellular arrays," which is not a disclosure of a biocompatible substrate associated with an electrode array.

Applicant's arguments are not found persuasive because Borkholder at col. 3, lines 15-19 discloses an embodiment wherein the biosensor comprises cells grown on a microfabricated array having micro-electrodes disposed over a

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substrate," which reads on an electrode "array" associated with a "biocompatible substrate."

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Jason Sims /

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631